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Author(s): Sarah Mills

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Department of Clinical Sciences

MSc In Weight Management

**‘Evaluation of an adult weight management service
delivered by pharmacies and
GP practices’**

Sarah Mills

Student No. 0870513

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Chester for the degree of Master of Science

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Declaration

This work is original and has not been submitted previously in support of a degree qualification or other course.

Signed:

Printed: SARAH MILLS

Date:

Evaluation of an adult weight management service delivered by pharmacies and GP practices

Author: Sarah Mills, BSc, RNutr

Purpose: This study aimed to determine whether an adult weight management programme delivered by pharmacies and GP practices in Birmingham was effective and if there was a difference between pharmacy and GP led programmes.

Method: In this repeated measures study (n=450) of a 12 week weight management programme consisting of weekly appointments and three follow up appointments delivered in pharmacies (n=183) and GP practices (n=267). Participants at baseline had a mean age of 42 (± 12.4) years, and mean BMI of 34.5 (± 6.0) kg/m² and were measured at baseline (n=450), 12 weeks (n=166) and 6 month follow up (n=82). Weight, BMI, waist circumference and quality of life (QoL) measurements were taken at each time point.

Results: Overall there was a significant decrease in weight (3.10kg (± 4.32)), waist (6.20cm (± 6.21)) and BMI (1.12kg/m² (± 1.76)) between baseline and 12 weeks (p=0.000), and baseline and six month follow up (p=0.000). With 39% of participants losing more than 5% of their weight and 54% losing more than 5cm from their waist at 6 month follow up. QoL significantly increased between baseline and 12 weeks (p=0.000), and baseline and six month follow up (p=0.000). GP led programmes had a significantly (p=0.043) higher percentage weight loss than the pharmacy led programmes at 12 weeks. However, the pharmacy led programme demonstrated significant (p=0.009) weight loss between completing the 12 week programme and 6 month follow up, compared to the GP led programme where weight increased. The pharmacy led programme had a considerably higher retention rate and resulted in a 4.03% (± 5.24) weight loss at follow up with significantly (p=0.019) more participants achieving more than 5% weight loss at the 6 month follow up compared with the GP led programme.

Conclusion: The adult weight management programme is effective, resulting in a significant decrease in weight, BMI and waist circumference and a significant increase in quality of life at 12 weeks and maintained 6 months post intervention. The pharmacy led programme appears more effective than the GP led programme demonstrating a significantly greater retention rate with a significant percentage of participants maintaining their weight loss 6 months post intervention.

Key Words: Obesity, Quality of Life, Weight Maintenance,

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Chapter 1 - Introduction

1.1 Rationale

As obesity prevalence and health care costs continue to increase, health care providers must prevent and manage obesity cost-effectively. Strategies for managing obesity need to be clinically effective and capable of dealing with large numbers of people.

GP practices and pharmacies are in unique positions within communities to deliver effective weight management interventions and reach a wide range of community members. Direction and evidence from the government white papers have resulted in a range of weight management interventions in GP practice and pharmacy emerging. However, attitudes and beliefs of practice and pharmacy staff can be a barrier to engagement and effective delivery, resulting in weight management still having a low priority in most GP practices and pharmacies due to lack of time, acknowledgement of responsibility, training, teaching materials, staff support and adequate reimbursement.

Few interventions have sustained impact on weight, hence the need for effective, practical weight management interventions for primary care. Furthermore, to the author's knowledge no study to date has directly compared the results from an intervention delivered within pharmacies and GP practices. In light of this, the present study will aim to determine if the weight management programme being delivered by pharmacies and GP practices in Birmingham results in significant weight loss and improved outcomes for obese adults. In addition it will ascertain whether there are any differences in the results between pharmacy and GP practice led services. The outcomes from the present research may have implications for the development and commissioning of future weight management programmes in primary care.

1.2 Literature Review

In the UK the rates of obesity have more than doubled in the last 25 years, and being overweight has become the norm for adults (Butland et al. 2007). In 2003/2004, the mean body mass index (BMI) of men and women in the UK general population was 27 kg/m², outside the healthy range of 18.5-25 kg/m² (Kopelman, 2007). The Health Survey for England (2008) data showed that 24% of men and 25% of women were obese (Craig, Mindell & Hirani, 2009), as defined by the World Health Organisation's (WHO) criteria of a BMI \geq 30 kg/m². A number of chronic medical conditions are associated with overweight and obesity, including type 2 diabetes, hypertension, coronary heart disease and stroke, metabolic syndrome, osteoarthritis and various cancers (Kopelman, 2007). There is a growing need for effective weight management initiatives in the UK to halt the rise in obesity.

Specifically, within the Heart of Birmingham, findings from the Heart of Birmingham Teaching PCT Public Health Report (2006) conducted in 2005/06 highlight that an estimated 43,000 adults are obese or overweight.

1.2.1 Why is obesity an issue?

The rising prevalence of obesity is a key public health concern with implications at an individual level of obesity-related disease and impaired quality of life, and at a population level a burden on healthcare resources (Lean, Han & Seidell, 1999; Must et al. 1999). Simple solutions to obesity are doubtful, given the complex interaction between the abundant availability of energy dense food, the constantly decreasing demand for energy expenditure in the modern world, and the influence of our genetic makeup. Treating people who are already obese is difficult; however, numerous systematic

reviews in recent years have demonstrated that diet, exercise, and behavioural approaches, used in combination, are effective management strategies, at least in the short term (Centre for Reviews and Dissemination, 1997; National Heart, Lung and Blood Institute, 1998).

The National Audit Office (Bourn, 2001) have estimated that the cost of obesity to the UK economy would reach £3.6bn by 2010. However, little is spent on obesity treatment, at £9.5 million annually in the UK in 2001 (Bourn, 2001), although this will rise with increased obesity prevalence and adoption of pharmacotherapy and bariatric surgery. If current trends continue, 36% of men and 28% of women aged 21-60 years in England will be obese by 2015 (Foresight, 2007). The cost of treating the consequences of obesity were approximately £1 billion in 2002 (House of Commons Health Committee, 2004) and could exceed £3 billion by 2015 (Foresight, 2007). In addition, in England it is estimated that obesity is responsible for 30,000 premature deaths per year and reduces life expectancy, on average, by 9 years (National Audit Office, 2002).

Obese people with no intervention will steadily gain further weight over time (Norman, Bild, Lewis, Liu & West, 2003). Norman, et al.'s (2003) longitudinal cohort study (n=3325) followed black and white men and women for 10 years. They found that a 10 year weight gain in young adults of both races and sexes tends to confer adverse changes in their levels of LDL-Cholesterol, HDL-Cholesterol, triglycerides, fasting insulin and blood pressure. This study did not rely on self-reported data and had a long follow up which makes the data more reliable.

1.2.2 Current initiatives that address obesity

While Government initiatives endeavour to reduce the rate of growth of obesity, and to tackle weight gain (Department of Health, 2008) with cross-sector collaboration, there is little indication

that the epidemic is reducing. The National Institute for Health and Clinical Excellence (NICE, 2006) recognises the importance of providing structured weight-management programmes, incorporating diet and behavioural measures where possible, and appropriate evidence based use of drugs and surgery. The effectiveness of intensive, resourced interventions is well documented (Norris et al., 2005), but sustainable evidence-based weight management is not universally offered within routine healthcare (Jolly et al. 2010).

The UK Government White paper, 'Choosing Health' (2004), identified insufficient provision of services for obesity. This may have stimulated development of new services because a survey of 344 primary care organisations in 2004 found that 51% had set up weight management services in primary care (Dr Foster, 2005). Many short term studies, usually of 6 months duration, have investigated weight loss. However, obesity is a chronic condition. Life-long management is required and long term studies of efficacy are most relevant (National Heart, Lung and Blood Institute, 1998).

Douketis et al. (2005) undertook a systematic review of controlled trials of weight loss interventions that had a follow up of at least 2 years. The trials that reported the outcomes of dietary and lifestyle therapy, found a mean (sd) weight loss of 3.5 (+/- 2.4) kg after 2-3 year follow up. However, nine of the sixteen trials reported loss to follow-up rates ranging from 31%-66% and 14 trials only reported the outcomes of study completers, therefore the effect of weight loss interventions were probably over-estimated. Systematic reviews have reported that combined diet and exercise interventions result in greater weight loss than dietary interventions alone, both in the short and long term (Shaw, Gennat, O'Rourke & Del Mar, 2006; Curioni & Lourenco, 2005). Curioni and Lourenco (2005) reported the outcomes at 1 year or more from 33 randomised controlled trials of diet, exercise or diet and exercise. Mean weight loss in diet-only trials was 4.5 +/- 11.3 kg, compared to 6.7 +/- 8.3kg in the trials of combined diet and exercise ($p=0.063$). However, a systematic review of trials from

the major commercial and self-help weight loss programmes in the USA concluded that much of the evidence was sub-optimal, with many lacking evidence, having poor quality design and high attrition rates (Gilden & Wadden, 2005).

The effectiveness of four commercial weight loss programmes was evaluated in a randomised controlled trial (Truby et al. 2006). This reported that all four diets (Dr. Atkins' new diet revolution, Slim-Fast plan, Weight Watchers pure points programme and Rosemary Conley's eat yourself slim diet and fitness plan) resulted in clinically significant weight loss (average 5.9 kg) over the six months of follow up. However, the trial excluded people with chronic medical conditions, such as coronary heart disease, obtained its participants via advertising and had an upper age limit of 65 years. This means that the sample is not typical of the population trying to lose weight and targeted by primary care. By 12 months, follow up was only 54% and many had changed diet programme. Weight loss at 12 months in those followed up ranged from 9.0-10.9 kg in the groups to which they were originally allocated.

1.2.3 What is a successful weight loss?

The initial objective in the management of obesity is to prevent further weight gain (Scottish Intercollegiate Guidelines Network, 1996). Once weight is stabilised the second objective is to achieve some level of weight loss (Bourn, 2001). Expectations and aspirations of both patients and practitioners in obesity treatment are often unrealistic which impacts on perceived success at individual service levels.

Health benefits have been reported with modest weight loss of 5-10% of baseline weight (Blackburn, 1995; Goldstein, 1992) from lifestyle interventions, including a reduction in progression to diabetes

of up to 58% over 4 years (Knowler et al., 2002; Tuomilehto et al., 2001), improved lipid, glucose and blood pressure levels (Dattilo, Kris-Etherton, 1992; Wing, Jeffery, 1995; Williamson et al., 2000) and a reduction in risk of cardiovascular disease (National Heart, Lung and Blood Institute, 1998; Anderson & Konz, 2001). Obesity management is also central to the prevention of CHD and cancer, the two main causes of death in the UK (Calle et al., 2003). It is essential that we identify the best ways to achieve and sustain such weight loss in the general population.

1.2.4 Quality of Life & Obesity

Additional to its etiologic role in many common medical conditions, obesity has profound adverse physical, social, and economic consequences that can negatively affect quality of life (QoL), an increasingly important outcome considered by patients, clinicians, and policymakers alike. Consequently, QoL has become an key endpoint assessed in studies of obesity and weight loss interventions.

Nanchahal et al. (2009) found a high proportion of participants of a weight management programme reporting anxiety and depression and problems with mobility, self-care, and carrying out usual activities. This has also been observed by Bjerkeset, Romundstad, Evans and Gunnell, (2008) whose cohort study (n=74,332) conducted in Norway found that raised BMI was associated with increased risk of depression. Raised BMI has also been associated with lower health-related quality of life in the UK (Sach et al., 2006) and USA (Jia & Lubetkin, 2005). Nanchahal et al. (2009) reported that weight loss was related to reduction in anxiety and depression, and improvement in weight-related symptoms, self-esteem, and quality of life.

Lean, Han and Seidell's (1999) cross sectional study (n=12905) used the SF-36 questionnaire to determine the differences in symptoms of respiratory insufficiency, low back pain, non-insulin-dependent diabetes mellitus, cardiovascular risk factors and physical functioning in relation to BMI. They found that most outcomes considered were significantly influenced by BMI. Between 25 to 30 kg/m², the prevalence of symptoms of obesity related diseases were all increased, and above 30 kg/m² greatly increased. Both men and women with BMI of 30 kg/m² or higher were twice as likely to have difficulties in performing a range of basic daily physical activities. This large Dutch sample can be generalised with caution to most western/white populations, however the study was limited by the age range (20-59 years). This supported by Sach et al.'s (2006) study (n=1865) which examined the relationship between BMI and health related quality of life (HRQL). They found patients with back pain, hip pain, knee pain, asthma, diabetes or osteoarthritis were also more likely to be obese. After controlling for other factors, compared to normal BMI patients, obese patients had lower HRQL. This study was carried out at one GP practice so may not be generalisable.

1.2.5 Weight Management in General Practice

GP Appointments

As gatekeepers to the health care system, general practitioners (GPs) can play a vital role in addressing obesity in their consultation. Two-thirds of the UK population visit their GP at least annually, so primary care is an important setting to tackle the obesity epidemic (Bourn, 2001). Primary care remains the public's preferred source of food and health information (Hiddink, Hautvast, van Woerkum, Fieren & Van't Hof, 1997) and there is evidence that patients' attitudes towards practice based lifestyle interventions are positive (Wallace, Haynes, 1984; Wallace, Brennan & Haines, 1987). Wallace, Brennan and Haines's (1987) study (n=62,153) revealed that 67% of

patients thought their GP should be interested in their lifestyle in relation to weight and 24% of women recalled receiving advice about weight. They concluded that patients are concerned about their lifestyles and most would welcome relevant counselling. The larger sample size makes it possible to generalise these conclusions, however the situation may have changed since this research was carried out. Furthermore, Galuska et al. (1999) used the Behaviour Risk Surveillance System to sample 12,835 adults classified as obese who had visited their physician for a routine check up during the previous 12 months. They found 42% of patients were advised to lose weight. These people were more likely to report trying to lose weight (79.5%) than those that were not advised (57.6%). This study is limited as patient reports may not accurately reflect the actions of the health professional, weight was self reported and some participants refused to participate which may bias the results. Stafford, Farhat, Misra and Schoenfeld (2000) cross sectional survey (n=55,858) also supports these findings.

There is compelling evidence that physician counselling and management of obesity treatment can be very effective in helping patients to undertake and sustain a weight management program (Kreuter, Chheda & Bull, 2000). Kreuter, Chheda and Bull's (2000) randomised controlled trial (n=915) with a 3 month follow up explored the potential 'priming effect' of physician advice of patient responses to behavioural change interventions. They found that patients who received physician advice to eat less fat or get more exercise prior to receiving intervention materials on the same topic were more likely to remember the materials, show them to others (51% vs 34%; OR=1.48, 95% CI=1.13-1.95), and perceive the materials as applying to them specifically (44% vs 31%; OR=1.30, 95% CI=0.98-1.72). They were also more likely to report trying to make changes to their diet and physical activity. This study relies on self report so may not accurately reflect behaviour change. However, when printed materials are made available, they may still be used infrequently (Booth, Nowson, Huang, Lombard & Singleton, 2006). Some interventions for

weight management have shown positive results, however these are often time intensive (Laws, 2004b).

The Department of Health (2002) stated that primary care should 'use every opportunity to promote healthy lifestyles' and should provide advice on diet, weight reduction and exercise. A survey of GPs and Practice Nurses reported by the National Audit Office identified numerous factors that they think would support them in the treatment of patients, including more information on effective interventions, availability of better materials for advising patients, and better training for staff (Bourne, 2001).

Obese populations attend general practice frequently (Counterweight Project Team, 2005b), incurring increased prescribing costs (Counterweight Project Team, 2005a). The Counterweight Project Team (2008c) quantified the influence of body mass index on prescribing costs, revealing that drug prescriptions rise from a minimum at BMI of 20 kg/m² and steeply above BMI 30 kg/m². They concluded that an effective weight management programme in primary care could potentially reduce prescription costs and lead to substantial cost avoidance. As in all economic analyses assumptions were made during this study which may limit this study being generalised.

GP & PN Attitudes and Beliefs

GPs and primary care nurses (PCNs) believe weight management is part of their role, but perceive their effectiveness as poor (Campbell et al., 2000; Laws, 2004b). Foster et al. (2003) found that the treatment of obesity was rated as significantly less effective than therapies for nine out of ten chronic diseases. Evidence also suggests that patients have a poor acceptance of such interventions and report physicians' traditional approach to weight management as unhelpful (Evans, 1999;

Wadden et al., 2000; Bramlage et al., 2004). The approaches most likely to support patients in achieving lifestyle change such as long-term follow-up, self-monitoring and social support are the least likely to be considered important, or practised in primary care (Campbell et al., 2000; Wadden et al., 2000; Bramlage et al., 2004).

Bramlage et al. (2004) examined doctors' (n=1,912) recognition and interventions, as well as patients (n=45,125) use and perceived effectiveness of weight loss interventions. They found doctors' recognition of overweight (20-30%) and obesity (50-65%) was low, patients' actual use of weight control interventions even lower (past 12 months:8-11%, lifetime:32-39%). Patient success rates were quite limited. It also showed that doctors seem to generally focus on obesity in older patients and particularly in those already manifesting with severe medical conditions. All the factors suggest that primary care management of obesity is largely deficient. It's possible that with the high prevalence of excess body weight in almost 60% of all patients, doctors perceive this to be 'normal' rather than an abnormal condition in most patients. This study had a number of strengths including the large sample size, representiveness, and looking at doctors' and patients' perspectives), however it was limited by self reported heights and weights.

Furthermore, health professionals including primary care clinicians frequently hold negative attitudes towards overweight or obese patients and this could obstruct practitioner and patient interaction (Foster et al., 2003). Primary care clinicians perceived ineffectiveness in helping patients lose weight and patients' failed weight loss attempts may result in perceived helplessness for clinician and patient. Foster et al.'s (2003) study assessed physicians' (n=620) attitudes towards obese patients. They found that more than 50% of physicians viewed obese patients as awkward, unattractive, ugly and noncompliant. However, most respondents agreed that a 10% weight reduction is sufficient to improve obesity related health complications. It also revealed that 54%

would spend more time working on weight management issues if their time was reimbursed appropriately. They concluded that primary care physicians view obesity as largely a behavioural problem and share our broader society's negative stereotypes about the personal attributes of obese persons. This study has a very low response rate (13%) and may have over represented physicians with an interest in obesity, so the results cannot be generalised.

Hoppe and Ogden (1997) examined PCNs (n=586) beliefs about obesity and their current practices. PCNs reported high confidence in their ability to give advice, however their expectations of patient compliance and actual weight loss were low. Failed weight loss was explained in terms of patient and not professional factors. They recommended that education programmes for practice nurses should not only include skills training but also emphasise self appraisal.

Patient Attitudes, Beliefs & Experiences

A study by Evans (1999) based on questionnaire responses from obese people (n=370) reported that 80% had previously been advised by their doctor to lose weight, but guidance on how to do this was generally judged to be poor. They concluded that ongoing help and support from doctors and other health care professionals is a key element in successful long term weight management. This is supported by Wadden et al.'s (2000) study which examined obese women (n=259) who participated in obesity trials at a university clinic. Participants were generally satisfied with the care they received for their general health, however, they were significantly ($p<0.001$) less satisfied with care for their obesity and with their physicians expertise in this area. However, the generalisability of these finding is open to question, given they were obtained in a research clinic.

Potter, Vu, and Croughan-Minihane's (2001) waiting room survey (n=410) revealed that patients would value more assistance with weight management in primary care, with the types of weight management assistance that patients most wanted from their physicians being: dietary advice, help with setting realistic weight goals and exercise recommendations. This study was limited to two practices so may not be able to be generalised.

Malterud and Ulriksen's (2010a) qualitative study (n=13) explored obese patients' experiences with GPs' management of their weight problems. They concluded that the challenge for the GP is to increase his or her competence in individualized and evidence-based counselling, while acknowledging the efforts needed by the patient to achieve permanent change, and shifting attention from shame to coping. The sample was small, however it was representative of diversity in terms of gender, age, and occupational background. Previous studies including provider perspectives have demonstrated that even well intended acts may turn out as humiliations (Malterud & Thesen, 2008). Everyone is somehow affected by the cultural messages concerning body weight, and prejudices and stereotypes are easily internalised by those affected (Malterud & Ulriksen, 2010b). This makes it unsurprising that patients feel reluctance when presenting with concerns about weight and ambivalence about the services received (Brown, Tompson, Tod & Jones, 2006).

Current Weight Management Programmes delivered in GP Practices

There are few studies on the effectiveness of weight management interventions delivered in routine primary care. Laws et al.'s (2004a) study (n=207) examined the current approaches to obesity management, 83% of GPs and 97% of practice nurses said they would raise weight as an issue with obese patients. However, few GPs (15%) reported spending up to 10 minutes in a consultation

discussing weight related issues, compared with practice nurses (76%). They concluded that obesity is under-recognised in primary care even in practices with an interest in weight management. Weight management seems to be based on brief opportunistic intervention undertaken mainly by the practice nurses. These results cannot be generalised due to the selective nature of the sample, as practices were already engaged in delivering a weight management service.

Despite consistent evidence for the important clinical benefits from moderate weight loss and weight maintenance in large scale clinical trials (Wing & Hill, 2001; Knowler et al., 2002; Tuomilehto et al., 2001), few studies have been published on the effectiveness of weight management interventions in primary care.

Studies have revealed that the provision of training alone to GPs and PCNs on nutrition and weight management can improve knowledge and perceived confidence, but does not change clinician behaviour or improve patient outcomes (Cadman & Findlay, 1998; Moore et al., 2003a). Cadman and Findlay (1998) assessed the change in PCN (n=30) nutrition knowledge and confidence when giving dietary advice to patients, following training from a dietitian. Nutrition knowledge increased significantly after training, with 88% of PCNs reporting having good or excellent confidence compared to 27% before training. The research area was confined to Dorset which may not be representative of the whole of the UK. Moore et al.'s (2003) cluster randomised trial (n=843) measured the difference in patients weight between practices which had and hadn't received a 4.5 hour training programme promoting an obesity management model . They showed some improvements in practitioner knowledge and practice however they found no difference in weight between the groups. The sample was biased towards women and retention was also an issue, however using a general practice as a unit of randomisation reduces the possibility of contamination between experimental arms.

One factorial randomised control trial (Nanchahal et al., 2009) (n=123) has been carried out to ascertain the effectiveness of a nurse-led multi-component weight management programme in general practice. One in three participants in the structured-support groups lost 5% or more of their initial weight, compared to less than one in five in the usual care group. Most participants reported that they found structured support helpful. They concluded that a structured lifestyle support package could make substantial contributions to improving weight management services. The patients in this study may have been selected or self-referred on keenness to lose weight which could bias the data.

While few models of best practice have been identified (Bourn, 2001), it is possible that a more comprehensive approach to empowering clinicians to change clinical practice is required. Multi-faceted interventions that target practice systems are more effective than single interventions (Grimshaw et al., 2001; Margolis et al., 2004). Margolis et al.'s (2004) randomised trial in 44 practices demonstrated how continuing education combined with process improvement methods is effective in increasing rates of delivery. This study was focused on preventive care for children so may not be generalisable, however, it gives an indication of what may work for obesity treatment and prevention.

The Counterweight Programme is an evidence and theory-based intervention for weight management delivered in family practice and other settings by PCNs and other health care workers, with initial guidance and facilitation by weight management advisers (Laws, 2004a). The programme was effective in an evaluation in 65 family practices (Table 1.) (The Counterweight Project Team, 2008). At 12 months, 45% of entrants provided data, with a mean 3kg loss from baseline. One in six patients entering Counterweight lost more than 5 kg at 12 months. With enhanced outcomes shown

in patients considered high attenders i.e. attending more than 66% planned appointments (Laws, 2004a; Counterweight Project Team, 2008c).

Table 1. Change in weight and BMI from baseline for 1419 patients enrolled on the Counterweight Programme for at least 12 months

Follow up attendance (months)	Attenders, n	Mean (SD) weight change, kg	Mean (SD) BMI change kg/m ²
3	775	-3.34 (3.53)	-1.22 (1.28)
6	548	-4.24 (5.19)	-1.55 (1.88)
12	642	-2.96 (6.64)	-1.08 (2.41)

(Counterweight Project Team, 2008b)

The Counterweight Project Team (2008b) study presents prospective evidence of an effective model of weight management for primary care. Weight change data compared favourably with those achieved in specialist research settings (Knowler et al. 2002). Despite no extra practice funding, more than two-thirds of practices enrolled new patients beyond 12 months, using time previously spent managing obesity more randomly. The Counterweight programme's strengths are that it is delivered in a naturalistic setting within routine primary care and its realistic evaluation on outcomes and process, with the continuous improvement methodology providing cheap, quick and tailored improvements. However, the study did not have a control group, less than one-quarter of patients were male and it did not look in detail at the impact on secondary outcomes. In addition practices were self-selecting, so they may have a particular interest in obesity. However, practices were broadly representative and included large practices, single-handed GP practices, rural and urban, and practices from high and low deprivation areas (Counterweight Project Team, 2008b).

The Counterweight Project team (2010) used the 2006 NICE obesity health economic model to analyse a primary care weight management programme. They concluded that weight management for obesity in primary care is highly cost effective. They suggest that reduced healthcare resources use could offset the total cost of providing the Counterweight Programme, as well as bringing multiple health and quality of life benefits.

1.2.6 Weight Management in Pharmacy

The White Paper *Pharmacy in England* (Department of Health, 2008b) supports a much more visible and active role for pharmacists in improving public health and specifically lists measurement of BMI and waist circumference, weight-management clinics and supply of medicines to help reduce weight among a range of activities through which pharmacies can contribute to overall strategies.

Reducing obesity, improving diet and increasing physical activity are priorities for the NHS in England and are included in the Government White Paper *Choosing Health Through Pharmacy* as one of 10 key priorities for community pharmacy (Department of Health, 2005). However, it has been implied that pharmacists have less interest in public health interventions which do not include a medicine and there is relatively little robust evidence to support community pharmacy weight loss programmes (Blenkinsopp, Anderson & Armstrong, 2010). Regardless of this, a variety of local and national services have recently been developed throughout England enabling community pharmacies to contribute to weight management (Royal Pharmaceutical Society of Great Britain, 2008); some are as part of a wider health check whereas others involve only the provision of advice and support (Anon, 2009, cited in Krska et al., 2010). Several schemes involve the use of patient group directions to facilitate the supply of prescription-only medicines as part of a weight-

management programme (Anon, 2007 cited in Krska et al., 2010; Anon, 2004 cited in Krska et al., 2010).

Community pharmacies could be ideal venues for weight-reduction programmes, as they provide access to a health professional without appointment over extended hours and in convenient locations. Many also have private consultation areas or rooms allowing personal issues to be discussed away from the shop floor (Krska et al. 2010). However, Anderson, Blenkinsopp and Armstrong's (2004) systematic review showed that usage of pharmacies for general health advice was low, with pharmacists being perceived as 'drug experts' rather than experts on health and illness. Users of community-pharmacy based health development initiatives express a high level of satisfaction, however extending the public's awareness and acceptance of the pharmacist's role in giving advice will be crucial.

Doucette et al.'s (2006) cross sectional study of community pharmacists using data from the 2004 National Pharmacist Workforce Survey showed that pharmacy care services (e.g. smoking cessation and health screening) were offered in relatively few community pharmacies, and were associated with innovativeness, pharmacy staff levels, and pharmacy setting.

Attitudes & Beliefs

Um, Armour, Krass, Gill and Chaar's (2010) qualitative study (n=20) explored pharmacists' opinions about the provision of weight management services in community pharmacy. Pharmacists undoubtedly perceived a role for pharmacy in weight management. Key facilitators to provision of service were accessibility and the perception of pharmacists as trustworthy healthcare professionals. The pharmacists proposed collaboration with other healthcare professionals to enable the provision

of a service incorporating diet, exercise and behavioural therapy. A programme that was not product centred, and supported by ethical marketing was favoured. Suitable training and accreditation were believed essential to ensuring the quality of such services. Barriers to the provision of high quality services identified were: remuneration, pharmacy infrastructure, client demand and the current market of product-centred programmes. This study is limited to Australian pharmacists, with all pharmacists interviewed already having a branded weight management programme within their pharmacy. However, it is supported by O'Donnell, Brown and Dastani's (2006) cross-sectional study (n=139) to assess barriers to the counselling of obese patients in pharmacies in Texas which identified the three top barriers as lack of time, lack of patient demand or expectations, and lack of reimbursement/ compensation. They also concluded that pharmacists' demographics and beliefs about obesity were significantly associated with their perceived barriers. Dastani, Brown and O'Donnell's (2004) study (n=400) of community pharmacists also identified that obesity counselling by pharmacists was positively correlated with their perceived comfort with counselling obese patients, confidence in achieving positive outcomes and the effectiveness of obesity management options. Both of these studies were carried out in Texas, so they are not generalisable to the UK.

Krska, Lovelady, Connolly, Parmar and Davie's (2010) study interviewed 177 members of the public and 49 community pharmacists about weight management services. Pharmacies and pharmacists were not favoured by members of the public as sources of advice on weight management. Most pharmacies provided prescriptions and over the counter weight loss products, with the frequency increasing with increasing deprivation of the pharmacy's location. Eight pharmacies provided a commercial weight loss programme and more than half had weighing scales. Krska et al. (2010) concluded that opportunities exist for extending NHS-led weight-management services from community pharmacies, but further research is required into the public's expectations of services to

support an increase in awareness and acceptance. The survey population for this study was the general public resident within Sefton PCT, rather than pharmacy users, and was not truly representative of the Sefton population. The method of data collection also required respondents to be present in a shopping centre during the day, thus resulting in bias towards the employed, males and the elderly.

Weight Management Interventions in Pharmacies

A recent uncontrolled trial of a weight-management service funded by the Department of Health in England found that 21% of patients recruited lost weight (Anon, 2009 cited in Krska et al., 2010). Studies outside the UK have demonstrated benefits of pharmacy weight management programmes with similar success rates (Ahrens et al., 2003; Lloyd et al., 2007). Some of these studies have involved small numbers of participants, which may suggest lack of awareness. Other work has also recognized that weight management, although considered by the public to be high priority for improving public health, was not considered an important pharmacy role (Morecroft & Krska, 2008). These studies suggest that more work is required to develop and evaluate community pharmacy weight-management services and to market them effectively.

As a result of the White Paper *Pharmacy in England* (Department of Health, 2008b), pharmacy contract negotiators recommended a government-funded national weight management service initiative in community pharmacies (Blenkinsopp et al., 2010). In 2007, the UK Department of Health funded a pilot weight management service delivered by pharmacies in the Coventry Primary Care Trust, which provided compelling evidence to support establishing weight loss programmes in pharmacy (Department of Health, 2008b). They recruited 150 patients, at follow up four (8 weeks) patients (n=102) had lost on average 0.618 of their BMI and an average 3.37cm of waist

circumference. Of these patients 68% had lost weight since recruitment. At 12 months (n=34), 30 patients had lost an average of 4.3kg in weight, 1.3kg/m² of BMI, and 6.7cm of waist circumference, with 26.5% of patients losing greater than 5% of their initial weight. The study involved 15 pharmacies, however 3 dropped out as a result of lack of engagement and recruitment issues, change in management and time pressures. (Tressler & Balcon, 2009; Coventry Primary Care Trust, 2008).

Several other studies have illustrated that community pharmacists' involvement in weight loss programmes has also been successful. Toubro, Dahlager, Hermansen, Herborg, and Astrup's (1999) retrospective study (n=269) evaluated a 12 week slimming course for obese subjects held at 19 Danish community pharmacies. The average weight loss was 5.3 and 6.2kg among females and males, respectively. At one year follow up 20% of the subjects who completed the course had maintained weight loss greater than 5kg. They concluded that the initial weight loss, and maintenance and drop out rate are comparable with results from general practitioners and hospital outpatient clinics, but the costs were substantially lower. Another example is the weight management service provided in a single pharmaceutical care centre on a college campus in the USA between 1996 and 2006 (Lloyd et al., 2007). Lloyd et al. (2007) retrospectively reviewed the data (n=289), reported a net mean weight loss of 3.6kg at 26 weeks. Ahrens, Hower and Best (2003) randomised controlled trial (n=95) compared a meal replacement (MR) program with a conventional reduced-calorie diet (RCD) for weight management using pharmacy as the setting and the pharmacist as the point of contact for dietary advice. During the 12 week weight loss phase both groups lost a significant amount of weight, with no significant difference (p=0.16) between groups. They concluded that successful weight management can be achieved in a pharmacy setting.

1.2.7 Conclusion

As obesity prevalence and health care costs continue to increase, health care providers must prevent and manage obesity cost-effectively. Few interventions have sustained impact on weight, hence the need for effective, practical weight management interventions for primary care. Strategies for managing obesity need to be clinically effective and capable of dealing with large numbers of people.

GP practices and pharmacies are in unique positions within communities to deliver effective weight management interventions and reach a wide range of community members. Direction and evidence from the government white papers have resulted in a range of weight management interventions in GP practice and pharmacy emerging. However, attitudes and beliefs of practice and pharmacy staff can be a barrier to engagement and effective delivery, resulting in weight management still having a low priority in most GP practices and pharmacies due to lack of time, acknowledgement of responsibility, training, teaching materials, staff support and adequate reimbursement.

1.3 Research Question

To determine whether an adult weight management programme delivered by pharmacies and GP practices in Birmingham was effective and if there was a difference between pharmacy and GP led programmes.

Chapter 2 - Methods

2.1 Participants

Participants (n= 450) taking part in the pharmacy and GP led weight management programmes being delivered in Heart of Birmingham Primary Care Trust (HoBtPCT) were recruited by pharmacies (n=183) and GP practices (n=267). The pharmacies and GP practices were recruited by HoBtPCT based on expressions of interest and location, and trained to deliver the weight management programme developed by HoBtPCT. Participants were all given a participant information sheet (Appendix 1).

All participants on the programme fulfilled one of the following criteria for BMI:

- Greater than 30 with no co morbidities
- Greater than 28 with co morbidities
- Greater than 25 for Asian patients with no co morbidities
- Greater than 23.5 for Asian patients with co morbidities

Participants had a mean BMI of 34.5 kg/m² ranging from 24.9 kg/m² to 57.4 kg/m². With the mean BMI for pharmacies being 33.3 kg/m² and the mean BMI for GP practices being 35.9 kg/m².

The participants consisted of 385 females and 65 males aged between 16 and 85 years, with a mean age of 42 years. Of those recruited by pharmacies (n=183) there were 158 females and 25 males aged between 17 and 85 years, with a mean age of 39 years. Of those recruited by GP practices (n=267) there were 227 females and 40 males aged between 16 and 77 years, with a mean age of 43 years.

Participants came from a wide range of ethnic backgrounds, with 85% from ethnic minority groups, with the majority from Pakistani origin (n=126) closely followed by Caribbean (n=87) and Indian (n=83).

Ethical approval for the present study was acquired from the Faculty of Applied and Health Sciences Research Ethics Committee at the University of Chester (Appendix 2). Informed consent was given from all of the participants involved (Appendix 3).

2.2 Study Design

The study was designed to determine if the weight management programmes were effective overall and if there was a difference between a pharmacy or GP practice led adult weight management service. The study followed a repeated measures design. The dependent measures were weight (kg), waist circumference(cm), BMI (kg/m²) and quality of life (SF-12). These measures were taken at the beginning of the intervention, at 12 weeks and at the 6 month follow up. The independent measure was the place of delivery, either pharmacy or GP practice.

2.3 Weight Management Programme Design

The adult weight management programme developed by HoBtPCT and delivered between January 2010 and June 2011 by trained pharmacy and GP practice staff consisted of 12 weekly individual appointments of 20-30 minutes in duration covering a range of topics (Appendix 4) to support participants to make long term lifestyle changes to facilitate and maintain weight loss. The main programme was followed by up to three follow up appointments at bimonthly intervals to offer continued support.

2.4 Procedures

2.4.1 Data Collection

Participation information sheets (Appendix 1.) and consent forms (Appendix 3.) were delivered (by hand) by the lead researcher to the pharmacy and GP practice staff who subsequently distributed them to all participants of the weight management programmes. Completed consent forms, including a unique reference number, were collected by the lead researcher from the pharmacy and GP practice staff.

The measurements and questionnaires were completed at baseline, 12 weeks and at 6 month follow up by trained pharmacy and GP practice staff as part of the weight management programme. Anonimised data was regularly sent back to HoBtPCT Public Health department to be input onto a database. The measurement and questionnaire data required for each participant was then

collected by the lead researcher from HoBtPCT Public Health department using a unique reference number allocated to each participant to replace any identifying information.

2.4.2 Measurement Procedures

Standard measurement procedures were used for all measurements throughout the study. (Appendix 5)

2.4.3 Quality of Life Questionnaire

The SF 12 health survey is a brief, reliable measure of overall health status (Ware et al., 2009). The SF-12 health survey is copyright by QualityMetric Incorporated. It measures eight domains of health: physical functioning, role limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health. It yields scale scores for each of these eight health domains, and two summary measures of physical and mental health: the Physical Component Summary (PCS) and Mental Component Summary (MCS). The SF 12 survey contains 12 items from the SF 36 health survey, and has been developed as a shorter alternative to the SF 36 where the 36 item form was too long.

Wee, Davis and Hamel (2008) compared the SF-36 and SF-12 health status questionnaires in patients with and without obesity. They concluded that SF-12 correlated highly with SF-36 in obese and non-obese patients and appeared to be a better measure of differences on QOL associated with BMI.

The SF-12 questionnaire (version 1) (Appendix 6) was administered at baseline (Week 1), at the end of the 12 sessions (Week 12) and at the end of the follow-up period (Week 15). SF-12 physical component summary (PCS) and mental component summary (MSC) scores were calculated using Quality Metric Health Outcomes Scoring Software v4.0.

2.5 Statistical Analysis

All data was analysed using the Statistical Package for the Social Sciences (SPSS) programme (Version 18.0) SPSS Inc, Chicago, IL, USA. Data used in this study was quantitative.

2.5.1 Descriptive Statistics

Descriptive statistics were carried out to understand the characteristics of the study population. The main dependant variables (weight, waist circumference, BMI and quality of life) were all ratio level data. Descriptive statistics were computed for weight, waist circumference, BMI and quality of life for the whole sample and for subsets of the sample according to where the intervention was delivered (pharmacy/GP practice). Descriptive statistics were also computed for gender, ethnicity and age range.

2.5.2 Inferential Statistics

Tests for normality and homogeneity of variance

Tests of normality and homogeneity of variance were used on the four main dependent variables, for each repeated measure and according to independent groups based on where the intervention was delivered (pharmacy/GP practice). The Shapiro-Wilk statistic was used to test normality, where the sample size was less than 100. The Kolmogorov-Smirnov statistic was used to test normality, where the sample size was more than 100 and the homogeneity of variance was assessed using Levene's statistic. This enabled the lead researcher to quote the appropriate descriptive statistics and to determine whether the data was eligible for undergoing parametric statistical testing.

When assessing the initial difference between study groups, weight, BMI, waist circumference and quality of life did not satisfy the test for normality and data was treated as non-parametric. Data analysis for this set was completed using the Mann Whitney U Test. Statistical significance was assessed at the 0.05 level.

Chi Square Test

To determine any difference between study groups for nominal level data (gender, ethnicity, age range), chi squared tests were used.

Independent T-test

Providing the assumptions of normal distribution and homogeneity of variance were both confirmed an independent t-test was used to test for differences between groups. Statistical significance was assessed at the 0.05 level. Mann Whitney U tests were used for non-normally distributed data. Normal distributions were not met so the non parametric equivalent, a Mann Whitney U Test was performed to determine any difference between study groups for weight, waist circumference, BMI, and quality of life at baseline, 12 weeks and follow up.

Mixed model ANOVA

The assumptions of normal distribution and homogeneity of variance were not met for the pharmacy group for weight, BMI or waist so a mixed model ANOVA with post-hoc analyses could not be used to compare the two independent groups and three repeated measures for difference in weight, waist, BMI and quality of life.

Repeated measures ANOVA

The assumptions of normal distribution and homogeneity of variance were met for the GP practice group for weight, BMI, waist and quality of life so a repeated measures ANOVA with post-hoc analyses was used to compare the three repeated measures for difference in weight, BMI, waist and quality of life. Mauchly's test of sphericity was used, the assumption for sphericity was not met so the 'Greenhouse-Geisser' statistic was used throughout the analysis.

Paired T-test

Providing the assumptions of normal distribution and were confirmed paired t-tests were carried out to test for differences between variables within the groups. For non-normally distributed data Wilcoxon Signed ranks tests were used. The Shapiro Wilk statistic was used as the sample sizes were

below 100. The assumption for normal distribution was only met for the GP data for waist and BMI measurements for the difference between week 1 and follow up and week 12 and follow up were normally distributed where a paired T-test was carried out. All other data looking at the difference between variables within groups did not meet the assumptions, so the Wilcoxon Signed rank test was used.

Chapter 3 - Results

3.1 Participants

A total of 450 patients enrolled on the programme, 166 (36.9%) completed the 12 week programme, and 82 (18.2%) completed the six month follow up appointment. Pharmacies enrolled 183 patients on the programme, 91 (49.7%) completed the 12 week programme, and 60 (32.8%) attended the six month follow up appointment. GP practices enrolled 267 patients on the programme, 75 (28.1%) completed the 12 week programme, and 22 (8.2%) attended the six month follow up appointment.

A significant difference was found at baseline between the GP and pharmacy groups for age ($p=0.001$), weight ($p=0.000$), BMI ($p=0.000$), BMI category ($p=0.000$) and waist ($p=0.003$). No significant difference was found between quality of life scores for PCS ($p=0.494$) and MCS ($p=0.393$) between GP and pharmacy groups.

Both GP and pharmacy programmes showed similar percentages of participants when split by gender (Figure 1). With the majority of participants being female for both programmes.

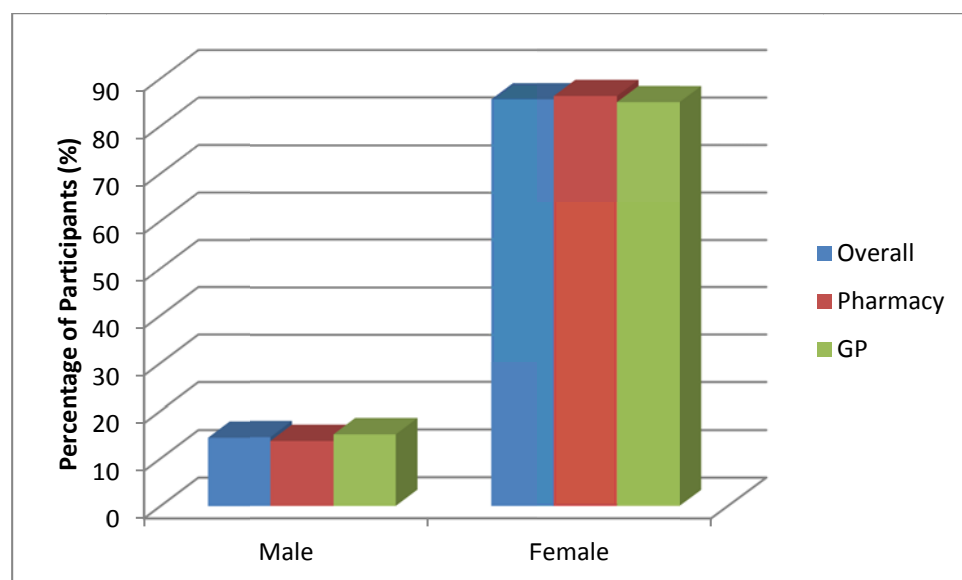


Figure 1. Gender of participants overall and separated for pharmacy and GP led programmes

The GP and pharmacy programmes were significantly ($p=0.003$) different for the age group of participants at recruitment (Figure 2). Pharmacies recruited more participants from the younger age groups.

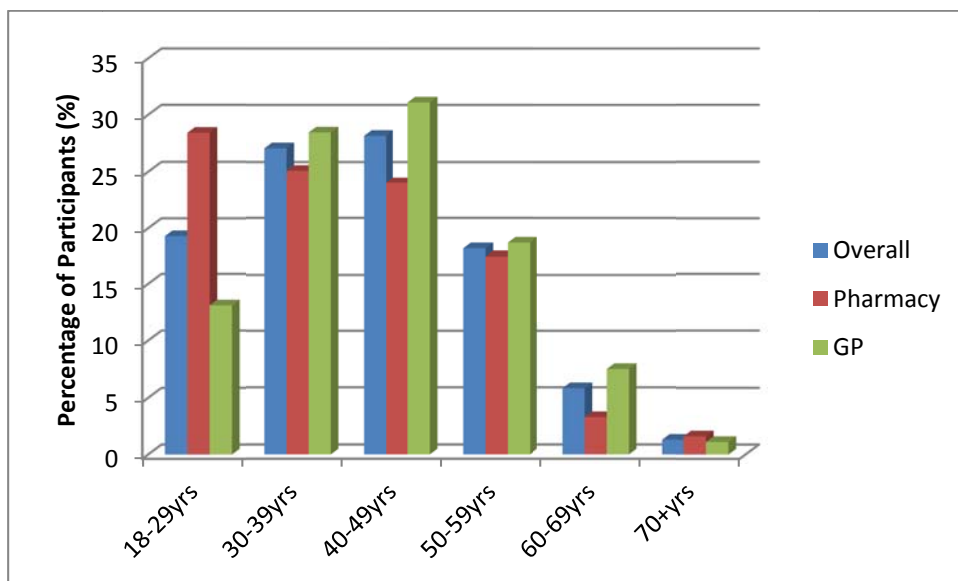


Figure 2. Age range of participants overall and separated for pharmacy and GP led programmes

The majority of participants recruited were from Pakistani, Indian and Caribbean origin. The GP and pharmacy programmes were significantly ($p=0.000$) different for the ethnicity of participants at recruitment (Figure 3). With pharmacies recruiting a considerably higher number of Pakistani participants than the GP practices.

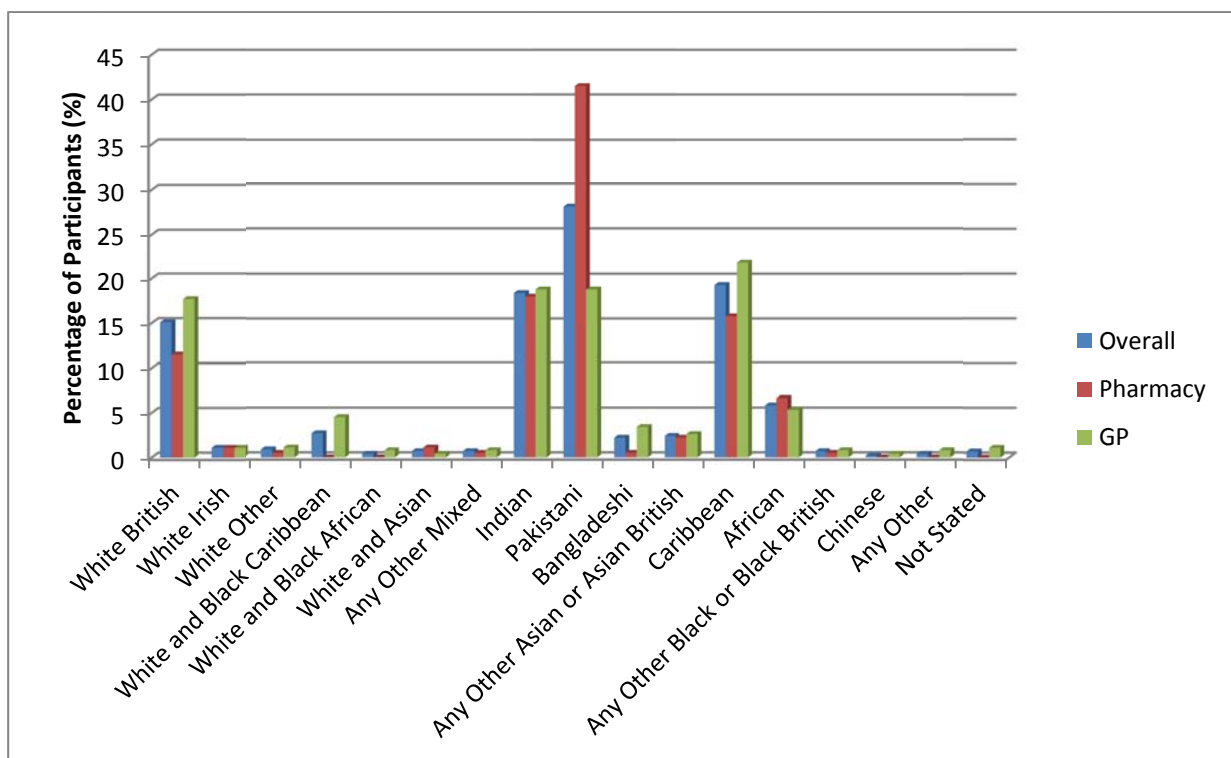


Figure 3. Ethnicity of participants overall and separated for pharmacy and GP led programmes

3.2 Weight

Overall the mean weight at baseline was 91.2kg (± 19.13), the mean weight at 12 weeks after completing the programme was 88.3kg (± 18.97) and the mean weight at 6 month follow up was 87.3kg (± 18.77). There was a significant decrease in weight between baseline and 12 weeks ($p=0.000$) and baseline and follow up ($p=0.000$). For patients participating in the pharmacy led programme the mean weight at baseline was 86.8kg (± 16.20), the mean weight at 12 weeks after completing the programme was 84.4kg (± 16.25) and the mean weight at 6 month follow up was 83.0kg (± 17.17). There was a significant decrease in weight between baseline and 12 weeks ($p=0.000$), baseline and follow up ($p=0.000$) and 12 weeks and follow up ($p=0.009$). For patients participating in the GP led programme the mean weight at baseline was 96.5kg (± 21.07), the mean weight at 12 weeks after completing the programme was 92.7kg (± 21.06) and the mean weight at 6 month follow up was 99.2kg (± 18.18). There was a significant decrease in weight between baseline and 12 weeks ($p=0.000$), and a significant increase in weight between baseline and follow up ($p=0.026$). There was a significant difference between the means for pharmacy and GP led programmes at baseline ($p=0.000$), 12 weeks ($p=0.004$) and follow up ($p=0.000$). Figure 4. Illustrates the differences in mean weight at baseline, 12 weeks and follow up.

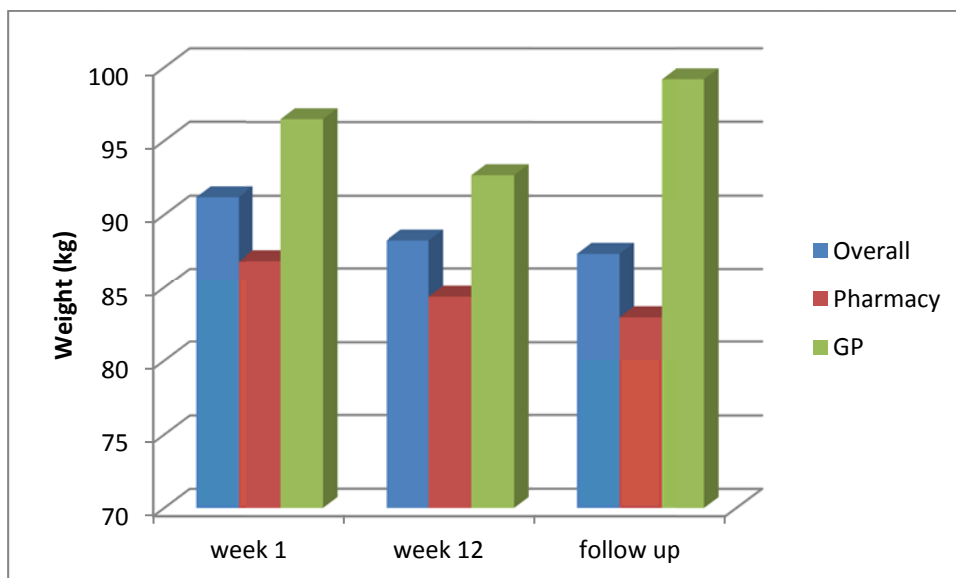


Figure 4. Mean weight at baseline, 12 weeks and follow up

Overall the mean weight loss after 12 weeks was 2.93kg (± 3.56) and at six month follow up was 3.10kg (± 4.32). For patients participating in the pharmacy led programme the mean weight loss after 12 weeks was 2.20kg (± 3.42) and at six month follow up was 3.40kg (± 4.28). For patients

participating in the GP led programme the mean weight loss after 12 weeks was 3.85kg (± 3.54) and at six month follow up was 2.3kg (± 4.45). Figure 5. Illustrates the mean weight loss at 12 weeks and follow up.

There was a significant difference ($p=0.010$) between the pharmacy and GP led programmes for weight loss at 12 weeks. There was not a significant difference ($p=0.094$) at follow up.

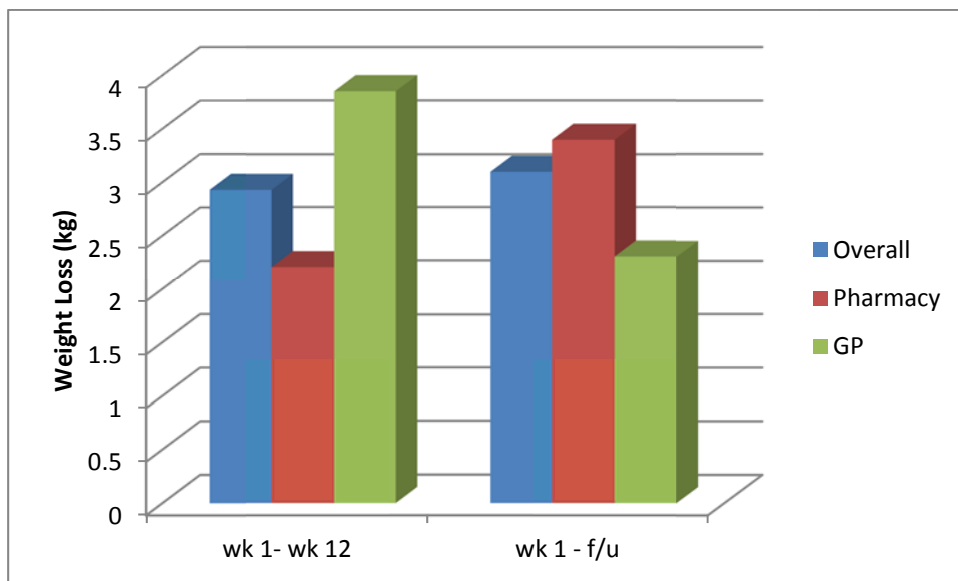


Figure 5. Mean weight loss at 12 weeks and follow up

Overall the mean percentage weight loss after 12 weeks was 3.22% (± 3.98) and at six month follow up was 3.54% (± 5.08). For patients participating in the pharmacy led programme the mean percentage weight loss after 12 weeks was 2.54% (± 4.03) and at six month follow up was 4.03% (± 5.24). For patients participating in the GP led programme the mean percentage weight loss after 12 weeks was 4.06% (± 3.78) and at six month follow up was 2.23% (± 4.47). Table 2 shows the percentage of patients losing weight as a result of the programme.

Table 2. Percentage of patients losing weight and losing more than 5% of their weight at 12 weeks and 6 month follow up

	Participant numbers		Percentage of patients losing weight		Percentage of patients achieving >5% weight loss	
	12 weeks	6 month follow up	12 weeks	6 month follow up	12 weeks	6 month follow up
Overall	166	82	86%	76%	27%	39%
Pharmacy led	91	60	86%	80%	22%	47%
GP led	75	22	87%	64%	33%	18%

At 12 weeks the GP led programmes had significantly ($p=0.043$) higher percentage weight loss than the pharmacy led programmes (Figure 6.). The pharmacy led programme resulted in significantly ($p=0.019$) more participants achieving more than 5% weight loss at the 6 month follow up compared with the GP led programme.

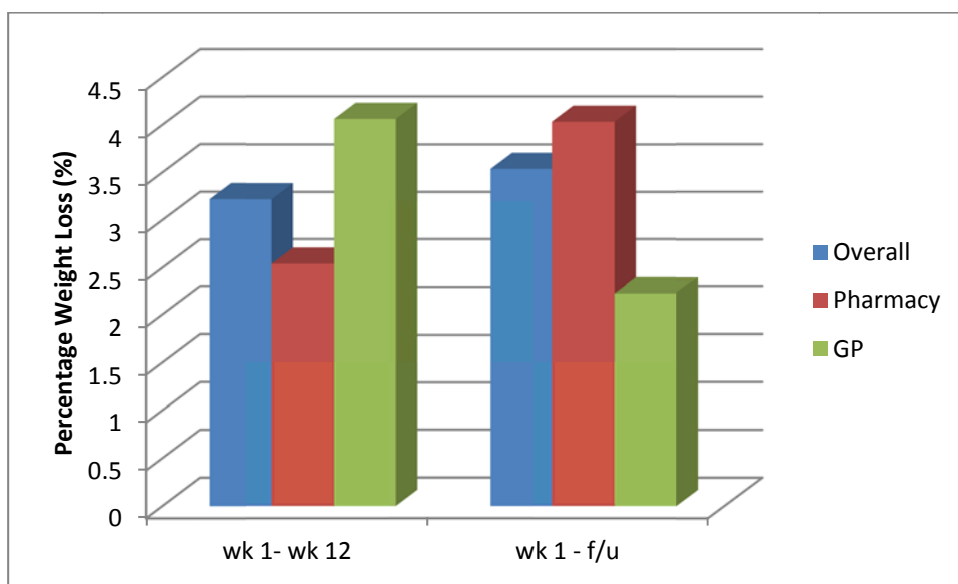


Figure 6. Mean percentage weight loss at 12 weeks and follow up

3.3 Body Mass Index

Overall the mean BMI at baseline was 34.5 kg/m² (\pm 6.38), the mean BMI at 12 weeks after completing the programme was 33.4 kg/m² (\pm 6.46) and the mean BMI at 6 month follow up was 33.2 kg/m² (\pm 7.76). There was a significant decrease in BMI between baseline and 12 weeks ($p=0.000$) and baseline and follow up ($p=0.000$). For patients participating in the pharmacy led programme the mean BMI at baseline was 33.3 kg/m² (\pm 6.04), the mean BMI at 12 weeks after completing the programme was 32.5 kg/m² (\pm 6.25) and the mean BMI at 6 month follow up was 31.9 kg/m² (\pm 7.80). There was a significant decrease in BMI between baseline and 12 weeks ($p=0.000$), baseline and follow up ($p=0.000$) and 12 weeks and follow up ($p=0.004$). For patients participating in the GP led programme the mean BMI at baseline was 35.9 kg/m² (\pm 6.54), the mean BMI at 12 weeks after completing the programme was 34.5 kg/m² (\pm 6.59) and the mean BMI at 6 month follow up was 36.8 kg/m² (\pm 6.54). There was a significant decrease in BMI between baseline and 12 weeks ($p=0.000$), and a significant increase between baseline and follow up ($p=0.001$). There was a significant difference between the means for pharmacy and GP led programmes at baseline ($p=0.000$), 12 weeks ($p=0.028$) and follow up ($p=0.006$). Figure 7. Illustrates the mean BMI at baseline, 12 weeks and 6 month follow up.

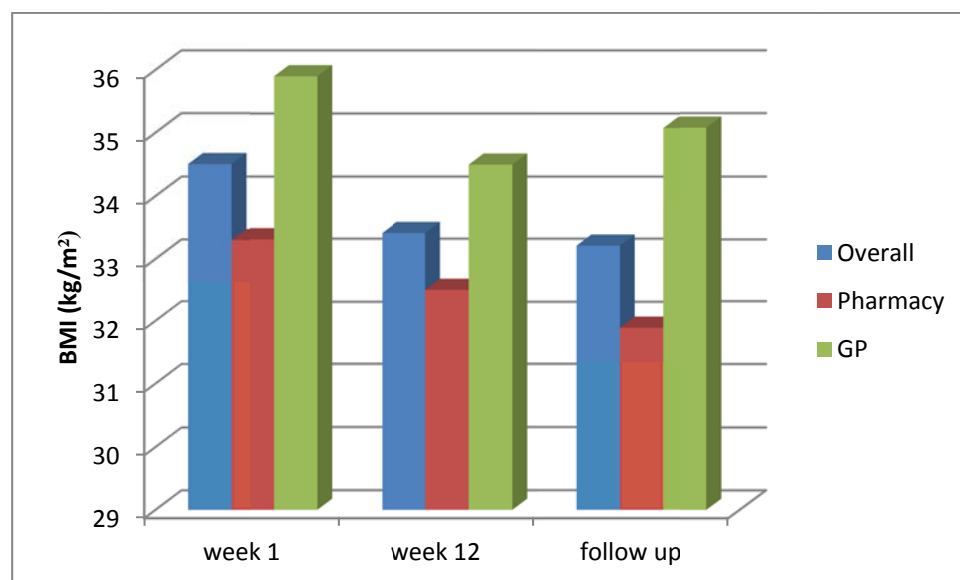


Figure 7. Mean BMI at baseline, 12 weeks and follow up

Overall the mean reduction in BMI after 12 weeks was 1.15 kg/m² (\pm 1.50) and at six month follow up was 1.12 kg/m² (\pm 1.76). For patients participating in the pharmacy led programme the mean reduction in BMI after 12 weeks was 0.82 kg/m² (\pm 1.30) and at six month follow up was 1.24 kg/m²

(± 1.78). For patients participating in the GP led programme the mean reduction in BMI after 12 weeks was 1.57 kg/m² (± 1.63) and at six month follow up was 0.82 kg/m² (± 1.69). Figure 8. Shows the mean reduction in BMI at 12 weeks and 6 month follow up.

There was a significant difference ($p=0.007$) between the pharmacy and GP led programmes for reduction in BMI at 12 weeks. There was not a significant difference ($p=0.069$) at follow up.

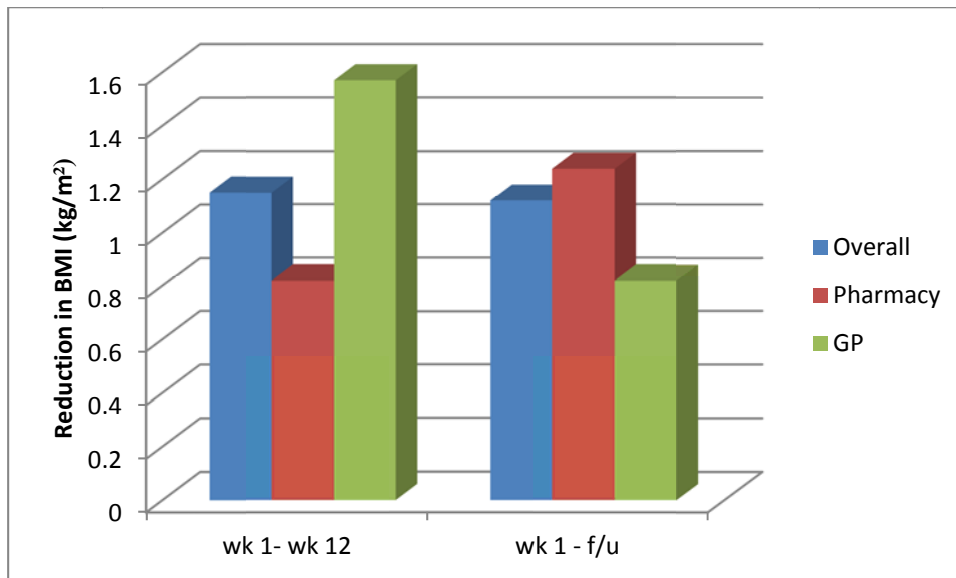


Figure 8. Mean reduction in BMI at 12 weeks and follow up

3.4 Waist Circumference

Overall the mean waist circumference at baseline was 106.3cm (± 15.63), the mean waist circumference at 12 weeks after completing the programme was 101.2cm (± 15.01) and the mean waist weight at 6 month follow up was 98.8cm (± 15.35). There was a significant decrease in Waist circumference between baseline and 12 weeks ($p=0.000$), baseline and follow up ($p=0.000$), and week 12 and follow up ($p=0.027$). For patients participating in the pharmacy led programme the mean waist circumference at baseline was 104.4cm (± 15.38), the mean waist circumference at 12 weeks after completing the programme was 100.0cm (± 13.80) and the mean waist circumference at 6 month follow up was 98.1cm (± 15.60). There was a significant decrease in waist circumference between baseline and 12 weeks ($p=0.000$), baseline and follow up ($p=0.000$) and 12 weeks and follow up ($p=0.009$). For patients participating in the GP led programme the mean waist circumference at baseline was 108.6cm (± 15.73), the mean waist circumference at 12 weeks after

completing the programme was 102.6cm (± 16.34) and the mean waist circumference at 6 month follow up was 100.5cm (± 14.89). There was a significant decrease in waist circumference between baseline and 12 weeks ($p=0.000$), baseline and follow up ($p=0.000$) and 12 weeks and follow up ($p=0.004$). There was a significant difference between the mean for pharmacy and GP led programmes at baseline ($p=0.003$). There was no significant difference between means for pharmacy and GP led programmes at 12 weeks ($p=0.334$) and follow up ($p=0.473$). Figure 9. Illustrates the mean waist circumference at baseline, 12 weeks and 6 month follow up.

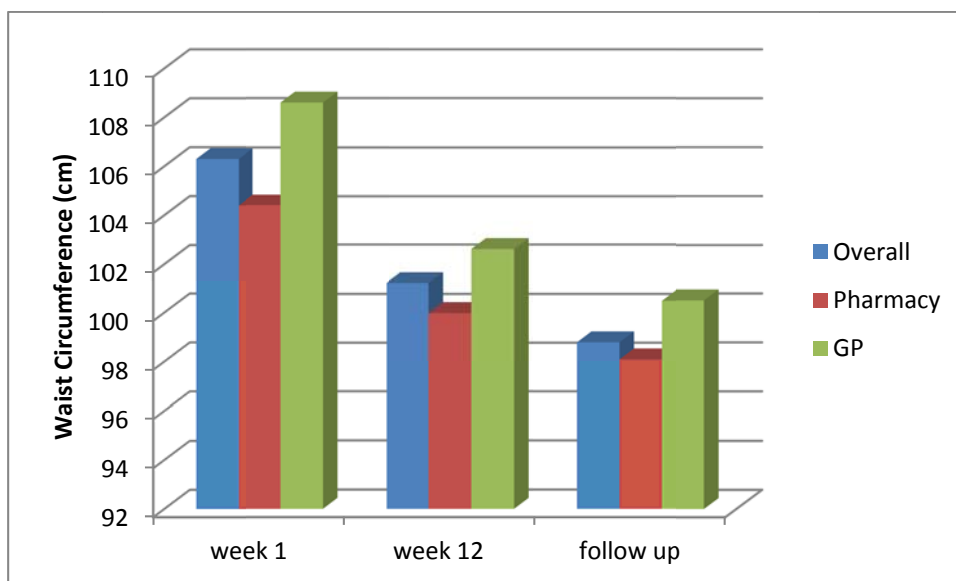


Figure 9. Mean waist circumference at baseline, 12 weeks and follow up

Overall the mean reduction in waist circumference after 12 weeks was 5.35cm (± 5.24) and at six month follow up was 6.20cm (± 6.21). With 88% and 85% of participants reducing their waist circumference at 12 weeks and 6 month follow up respectively (Table 3). For participants in the pharmacy led programme the mean reduction in waist circumference after 12 weeks was 4.88cm (± 4.59) and at six month follow up was 6.51cm (± 6.22). With 89% and 87% of participants reducing their waist circumference at 12 weeks and 6 month follow up respectively (Table 3). For participants in the GP led programme the mean reduction in waist circumference after 12 weeks was 5.94cm (± 5.94) and at six month follow up was 5.36cm (± 6.25). With 87% and 82% of participants reducing their waist circumference at 12 weeks and 6 month follow up respectively (Table 3). Overall 52% and 54% of participants lost more than 5cm from their waist circumference at 12 weeks and 6 month follow up respectively. Figure 10. Shows the mean reduction in waist circumference at 12 weeks and 6 month follow up.

There was no significant difference between the pharmacy and GP led programmes for reduction in waist circumference at 12 weeks ($p=0.074$) or at follow up ($p=0.247$).

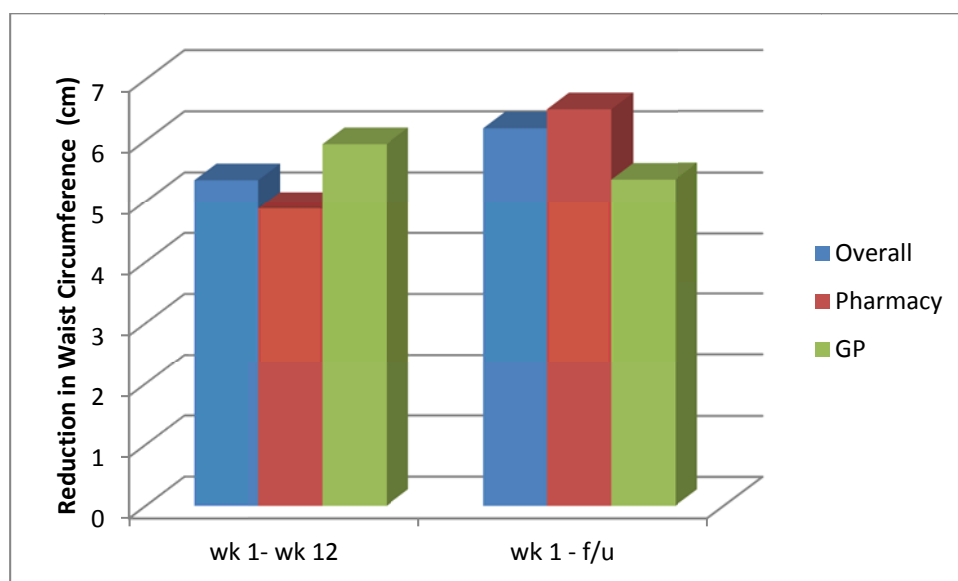


Figure 10. Mean reduction in waist circumference at 12 weeks and follow up

Table 3. Percentage of patients reducing their waist circumference and losing more than 5cm at 12 weeks and 6 month follow up

	Participant numbers		Percentage of patients reducing their waist circumference		Percentage of patients losing >5cm from their waist circumference	
	12 weeks	6 month follow up	12 weeks	6 month follow up	12 weeks	6 month follow up
Overall	166	82	88%	85%	52%	54%
Pharmacy led	91	60	89%	87%	47%	58%
GP led	75	22	87%	82%	57%	41%

3.5 Quality of Life

SF-12 physical component summary (PCS) and mental component summary (MSC) scores were calculated using Quality Metric Health Outcomes Scoring Software v4.0. As a number of programme participants had not completed the questionnaire at one or more of the data collection

points, results were tabulated for two pools of participants. The first pool consisted of participants who had completed the SF-12 questionnaire at both baseline and week 12 (n=154) and the second pool of participants who had completed the SF-12 questionnaire at both Week 1 and 6 month follow up (n=64). In addition, the week 12 scores for the participants who had completed the SF-12 questionnaire at both week 1 and 6 month follow up were also calculated. There were a number of cases where a participant has completed a questionnaire in week 12 but not week 1 (n=11) or at 6 month follow up but not week 1 (n=4).

Average PCS and MCS values for pharmacy and GP led programmes, and overall were calculated and shown in table 4 for week 12 and table 5 for 6 month follow up. The baseline values for each site will vary between week 12 and 6 month follow up owing to differences in the number of patients completing the questionnaire in week 12 and follow up. An increased PCS or MCS value indicates an improved quality of life.

Table 4. Average PCS and MCS values at baseline and Week 12

	Number	PCS (week 1)	PCS (week 12)	MCS (week 1)	MCS (week 12)	Change PCS (week 12)	Change MCS (week 12)
Pharmacy	85	44.77 (±9.32)	49.42 (±9.97)	49.18 (±7.08)	53.49 (±8.44)	4.41	4.08
GP	69	43.68 (±10.35)	48.02 (±10.15)	47.97 (±9.41)	54.25 (±7.08)	4.29	6.23
Overall	154	44.28 (±9.78)	48.79 (±10.04)	48.64 (±8.20)	53.83 (±7.84)	4.35	5.04

Table 5. Average PCS and MCS values at baseline and 6 month follow up

	Number	PCS (week 1)	PCS (week 15)	MCS (week 1)	MCS (week 15)	Change PCS (week 15)	Change MCS (week 15)
Pharmacy	44	43.81 (± 10.26)	52.75 (± 8.18)	47.59 (± 8.64)	52.10 (± 6.73)	3.78	-0.64
GP	20	39.47 (± 11.75)	48.12 (± 11.26)	45.70 (± 10.46)	56.96 (± 5.58)	6.23	8.85
Overall	64	42.45 (± 10.84)	51.30 (± 9.41)	47.00 (± 9.21)	53.62 (± 6.74)	4.55	2.32

Overall there was a significant increase in PCS and MCS score between baseline and 12 weeks ($p=0.000$) and a significant increase in PCS between baseline and follow up ($p=0.000$). For patients participating in the pharmacy led programme there was a significant increase in PCS ($p=0.000$) and MCS ($p=0.001$) score between baseline and 12 weeks and a significant increase in PCS between baseline and follow up ($p=0.017$). For patients participating in the GP led programme there was a significant increase in PCS and MCS score between baseline and 12 weeks ($p=0.000$) and a significant increase in PCS ($p=0.006$) and MCS ($p=0.001$) scores between baseline and follow up.

There was no significant difference between the mean's for pharmacy and GP led programmes at baseline (PCS $p=0.494$; MCS $p=0.393$), 12 weeks (PCS $p=0.378$; MCS $P=0.555$) and PCS for follow up ($p=0.452$). There was a significant difference between means for pharmacy and GP led programmes for MCS ($p=0.004$) at follow up.

Not all programme participants completed the SF-12 questionnaire at the three data collection points. The overall PCS and MCS score pattern for the 64 participants who undertook SF-12 questionnaires in all three data collection weeks is shown in Figure 11.

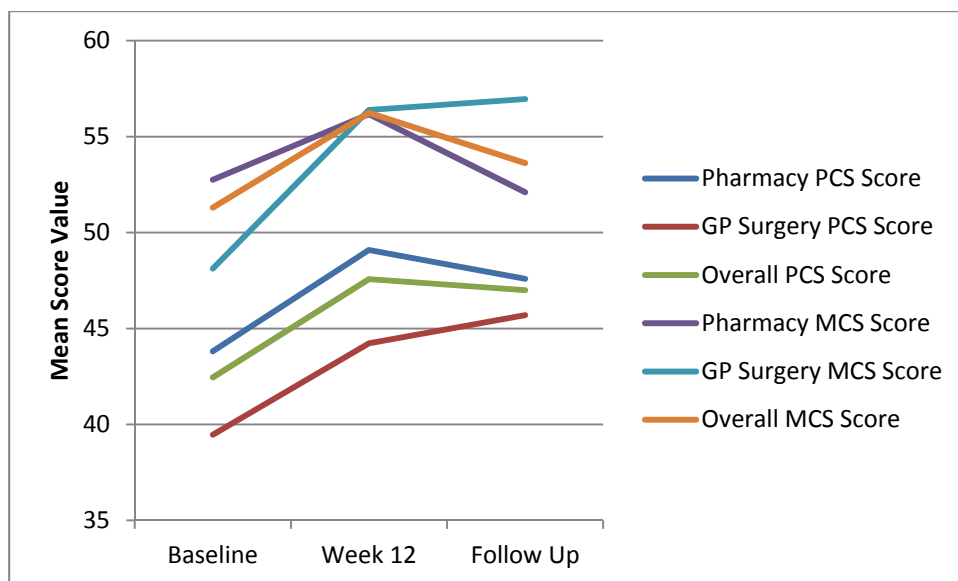


Figure 11. The change in mean PCS and MCS scores for pharmacy participants, GP surgery participants and overall at baseline, 12 weeks and follow up for the follow up analysis pool (n=64).

Chapter 4 - Discussion

4.1 Summary of the main findings

This study aimed to determine whether an adult weight management programme delivered by pharmacies and GP practices in Birmingham was effective and if there was a difference between pharmacy and GP led programmes.

Overall the adult weight management programme delivered in GP practices and pharmacies showed:

- A significant decrease in weight, waist and BMI between baseline and 12 weeks ($p=0.000$), and baseline and six month follow up ($p=0.000$).
- A significant increase in quality of life scores between baseline and 12 weeks ($p=0.000$), and baseline and six month follow up ($p=0.000$).
- A mean weight loss of 3.10kg (± 4.32) with 39% of participants losing more than 5% of their weight at 6 month follow up.
- A mean reduction in BMI of 1.12kg/m² (± 1.76)
- A mean waist circumference reduction of 6.20cm (± 6.21) with 54% of participants losing more than 5cm from their waist circumference at 6 month follow up

Comparison of pharmacy and GP led groups showed:

- A significant difference between GP and pharmacy led programmes for weight loss ($p=0.010$) and BMI change ($p=0.007$) between baseline and 12 weeks.
- GP led programmes had a significantly ($p=0.043$) higher percentage weight loss than the pharmacy led programmes at 12 weeks.
- Participants of the pharmacy led programme demonstrated significant ($p=0.009$) weight loss between completing the 12 week programme and 6 month follow up. Compared to participants of the GP led group whose weight increased.
- The pharmacy led programme resulted in significantly ($p=0.000$) higher percentage weight loss (4.03%) and significantly ($p=0.019$) more participants achieving more than 5% weight loss at the 6 month follow up compared with the GP led programme
- Retention rate for the pharmacy led programme was considerably higher than the GP led programme.

These results show the adult weight management programme is effective and that there are some marked difference between the results for pharmacy and GP led programmes.

There have been no studies published that have evaluated the same weight management programme being delivered in pharmacies and GP practices simultaneously. So the overall results cannot be easily compared with previous studies. However there are a limited number of studies for pharmacy led and GP led weight management interventions separately which can be compared with the individual groups results.

4.2 Participants

GP practices (n=267) recruited considerably more patients than pharmacies (n=183) onto the weight management programme. This may have been because patients routinely attend GP practices for advice about their health, so it was easier for the GP or practice staff to raise the issue of weight as patients are more open to advice and suggestions made by health care professionals. The majority of pharmacy customers do not visit the pharmacy for health advice, so the pharmacy staff have to think of different ways to engage the customer, for example through offering free BMI checks or using the Medicines Use Review to raise the issue of overweight. In addition to GP staff being familiar with delivering one to one appointments, whereas pharmacy staff may not be, so also find it harder to promote.

Overall 36.9% of patients completed the 12 week programme. A considerably higher percentage of pharmacy patients (49.7%) completed the 12 weeks compared to GP patients (32.8%). With a similar result for 6 months follow up with 28.1% of pharmacy patients and 8.2% of GP practice patients attending at 6 months. This may have been as a result of the pharmacy being at the centre of a community and the relationship the pharmacy staff build with their customers. Customers will visit a pharmacy regularly for a range of reasons, so pharmacy staff will have the opportunity to remind them about their appointments and informally offer them support, and reassure them if they have not attended for a few weeks. In a GP practice a patient may get a phone call if they don't attend an appointment, but this probably won't be followed up any further.

Coventry Primary Care Trust's (2008) pharmacy pilot had a different structure to the current 12 week programme, with fewer visits spread across a 12 month period. However they retained 31.8% of their patients at the equivalent of 6 month follow up (9th appointment), which is comparable to the pharmacies in the current study. The Counterweight Project Team's (2008b) study reported 54.6% retention at 12 weeks and 38.6% retention at 6 months which is not comparable to the GP practices in the current study whose retention rate was much lower. The Counterweight Project Team (2008b) recruited GP practices from across the country, including large practices, single-handed GP practices, rural and urban, and practices from high and low deprivation areas. The current study was carried out in central Birmingham which is an urban area of high deprivation which may have had an impact on the retention and other results.

The average age in the current study was 42 years which was considerably lower than the Counterweight Project Team's (2008b) study at 49.4 years and the Coventry Primary Care Trust's (2008) pilot at 50.2 years. The difference is likely to be due to the current study's urban city centre population having a lower average age compared to England (Birmingham City Council, 2010).

There were significantly more females than males who enrolled on the programme, with 14% of the participants being male. This was lower than the Counterweight Project Team (2008b) study (23%) and the Coventry Primary Care Trust (2008) pilot (33%). This may have been due to the majority of staff trained to deliver the programme being female, so they found it easier to approach female clients.

In the current study 85% of participants enrolled were from an ethnic minority background, with the majority from Pakistani, Caribbean or Indian origin. The only similar study that recorded ethnicity was the Coventry Primary Care Trust (2008) pilot which recorded 25% of their participants being from an ethnic minority background. This level of ethnic minority reflects the demographics of the Heart of Birmingham Primary Care Trust (2010) area.

4.3 Weight

The pharmacy led programme had a slower start, however the weight loss achieved was sustained. Whereas the GP practice led programme showed a faster weight loss initially but it was not sustained.

Participation in a 12 week adult weight management programme resulted in a significant weight loss of 2.93kg (± 3.56) at 12 weeks ($p=0.000$) and 3.10kg (± 4.32) at 6 month follow up ($p=0.000$). This equates to a reduction in weight of 3.22% (± 3.98) at 12 weeks and 3.54% (± 5.08) at 6 months follow up. Completion of the 12 week weight management programme resulted in significant weight loss maintained to 6 months post intervention. However, it is clear the weight loss achieved will not yield the health benefits of losing 10% of initial body weight described by Jung (1997) at these time points.

There was a significant difference in weight loss between the pharmacy and GP led programmes at 12 weeks ($p=0.010$), but no significant difference at 6 month follow up. The average weight loss for GP led programmes was 3.85kg (± 3.54). A significantly ($p=0.043$) higher percentage weight loss of 4.06% (± 3.78) between baseline and 12 weeks compared to pharmacies at 2.54% (± 4.03). The Counterweight Project Team's (2008b) study ($n=1419$) of a 12 week weight management programme delivered in GP practices showed a comparable weight loss at 12 weeks of 3.34kg (± 3.53).

However at 6 month follow up the pharmacy led programme demonstrated significant ($p=0.009$) weight loss between 12 weeks and 6 month follow up. Compared to participants of the GP led group whose weight increased. Pharmacies achieved 3.40kg (± 4.28) or 4.03% (± 5.24) weight loss at 6 month follow up compared with GPs who achieved 2.3kg (± 4.45) which is 2.23% (± 4.47). There are very limited studies that have reported 6 month follow up data for pharmacy led weight management interventions, Lloyd et al.'s (2007) study ($n=289$) in the USA showed a mean weight loss of 3.6kg at 26 weeks which is comparable to the current study. The 12 month follow up results are reported in a number of other studies with one UK study (Coventry Primary Care Trust, 2008) of a pilot pharmacy based obesity management service showing 30 of 34 patients had lost 4.3kg and a 12 week programme ($n=269$) and a study in Danish pharmacies (Toubro et al., 1999) demonstrated 5.3kg and 6.3kg weight loss among females and males, respectively. These results cannot be directly compared, and the UK study has a very small sample size only including those patients that lost weight, whereas the current study includes all patients that are enrolled on the programme. If the weight loss in the pharmacy led programme continues as it has over the first 6 months, it is possible that the results could be comparable and the patients could go on to achieve the 10% weight loss that brings numerous health benefits, however, further follow up is required.

The Counterweight Project Team (2008b) results can be compared with the GP led programme, they demonstrated a weight loss of 4.24kg (± 5.19) at 6 months for GP practices which is significantly higher than the results from the current study. This may have been as a result of the small sample size ($n=22$) for the 6 month follow up for the GP led programme being compared with a considerably larger sample size.

Overall 39% of participants lost more than 5% of their body weight at 6 month follow up.

The pharmacy led programme resulted in 47% of participants achieving more than 5% weight loss at the 6 month follow up, significantly ($p=0.019$) more than the GP led programme, with 18% of participants. The pharmacy led results cannot be compared directly as data is not available for 6 months follow up, however the Coventry Primary Care Trust (2008) pilot ($n=34$) showed 26.5% of participants losing more than 5% of their initial body weight at 12 months and Toubro et al. (1999) demonstrated 20% of subjects maintaining 5% weight loss at 12 months, so at 6 months the pharmacy led programme compares favourably but a 12 month follow up would be required to directly compare the results. The GP led programme results do not compare favourably to The Counterweight Project Team's (2008b) study which demonstrated 26.1% of participants achieving >5% weight loss at 12 weeks, 38% achieving >5% weight loss at 6 months and 30.7% at 12 months. However, these results are very similar when compared to the overall results, including pharmacy and GP practice, of the current study.

4.4 Body Mass Index

BMI is used to classify the degree of a patient's obesity (NICE, 2006). A BMI of $\geq 25\text{kg/m}^2$ is classified as overweight and a BMI of $\geq 30\text{kg/m}^2$ is classified as obese. Lower thresholds are used for patients of South Asian origin. The mean BMI of patients at baseline was 34.5kg/m^2 (± 6.38), so classified as obese. Campbell and Haslam (2005) argue that BMI was never designed to be used to assess individual's weight status, as it reflects both fat and fat free components of body mass. However, it has become the usual gold standard for defining overweight.

Participation in the 12 week adult weight management programme resulted in a significant reduction in BMI of 1.15 kg/m^2 (± 1.50) at 12 weeks ($p=0.000$) and 1.12 kg/m^2 (± 1.76) at 6 month follow up ($p=0.000$). Completion of the 12 week weight management programme resulted in significant reduction in BMI maintained to 6 months post intervention.

The GP led programme's BMI reduction was significantly ($p=0.007$) higher than the pharmacy led programme at 12 weeks, but no significant difference was found at 6 month follow up. At 12 weeks the average reduction in BMI for GP led programmes was $1.57 \text{ kg/m}^2 (\pm 1.63)$ compared with $0.82 \text{ kg/m}^2 (\pm 1.30)$ for pharmacies. At 12 weeks the Counterweight Project Team (2008b) study in GP practices found a reduction in BMI of $1.22 \text{ kg/m}^2 (\pm 1.28)$, which is lower than the GP programme result in the current study. Coventry Primary Care Trust's (2008) pharmacy pilot demonstrated a comparable BMI reduction of $0.7 \text{ kg/m}^2 (\pm 1.28)$.

However at 6 month follow up the pharmacy led programme demonstrated significant ($p=0.004$) reduction in BMI between 12 weeks and 6 month follow up, compared to participants of the GP led group where BMI increased. Resulting in pharmacies achieving $1.24 \text{ kg/m}^2 (\pm 1.78)$ reduction in BMI at 6 month follow up compared with GPs who achieved $0.82 \text{ kg/m}^2 (\pm 1.69)$. Again, Coventry Primary Care Trust's (2008) pharmacy pilot demonstrated a comparable BMI reduction of $1.3 \text{ kg/m}^2 (\pm 1.28)$, but at a 12 month time point, however the Counterweight Project Team (2008b) reported a BMI reduction of $1.55 \text{ kg/m}^2 (\pm 1.88)$ at 6 months which is significantly higher than the current study. This may have been as a result of the small sample size ($n=22$) for the 6 month follow up for the GP led programme being compared with a considerably larger sample size.

4.5 Waist Circumference

NICE (2006) recommend measuring waist circumference in patients with a BMI less than 35 kg/m^2 to assess health risks. A waist circumference $\geq 80\text{cm}$ for females and $\geq 94\text{cm}$ for males signifies an increased risk. The mean waist circumference of patients at baseline was $106.3\text{cm} (\pm 15.63)$, so patients had an increased risk.

Participation in the 12 week adult weight management programme resulted in a significant reduction in waist circumference of $5.35\text{cm} (\pm 5.24)$ at 12 weeks ($p=0.000$) and $6.20\text{cm} (\pm 6.21)$ at 6 month follow up ($p=0.000$). Completion of the 12 week weight management programme resulted in significant reduction in waist circumference maintained to 6 months post intervention. There was no significant difference between the GP practice and pharmacy programmes for waist circumference reduction at 12 weeks or 6 months.

There are a very limited number of studies that can be compared for waist circumference as this measure is not as commonly reported in similar studies. The Coventry Primary Care Trust (2008)

pilot study reported a 3.37cm and 6.7cm reduction at 8 weeks and 12 months respectively, lower than the current study at 12 weeks and comparable at follow up.

4.6 Quality of Life

Analysis of the data indicates a statistically significant increase in both PCS and MCS quality of life scores occurs in participants during the first twelve weeks of the programme. The increases seen do not differ in magnitude between the participants from pharmacies and those from GP surgeries. This increase in scores is maintained for participants who undertook their programme at the GP surgery and for the PCS scores for those participants who undertook the programme at the pharmacy. However, the data indicate that the mean MCS score for pharmacy participants does not maintain its increase by Week 15.

No studies have been identified which use the SF-12 health survey to evaluate a weight management programme. However, Lean, Han and Seidell's (1999) cross sectional study (n=12905) demonstrated that quality of life is significantly influenced by BMI. This is supported by Sach et al.'s (2006) study (n=1865) which examined the relationship between BMI and health related quality of life (HRQL). This research supports the results from the current study as overall the BMI of participants has decreased, so quality of life would be expected to increase as a result of the 12 week weight management programme.

4.7 Limitations of the Study

While the results of this evaluation show some useful findings. There are a number of limitations that should be taken into consideration.

Study design

No control group was used in this study, which prevented comparison with patients that had received no intervention. This was not an option in the current study due to the aims of the Primary Care Trust who commissioned the programme and the ethical implications of not offering a service to patients who had expressed an interest.

Sampling

A random sample of the population was not used in this study, instead participants were recruited by the GP practice and pharmacy staff by self-selection to participate in the weight management programme. These patients are more likely to be more motivated to make lifestyle changes than the general population. The GP practices and pharmacies expressed an interest and chose to take part in the programme so are likely to be those that are more interested in the area of weight management and more motivated to deliver a successful weight management service. Both these factors will influence the degree to which the results can be generalised.

Participants

The small sample size at the 6 month follow up for GP practices, and the small percentage of men that were recruited to the programmes mean that results are not generalizable.

Data collection

Data was only collected until 6 months post intervention. To be able ascertain long term outcomes and to directly compare the results of other similar studies an additional follow up at 12 months would be required. In addition the study was reliant on accurate quality of life data being completed by the participant. Self-reporting has the potential for inaccuracies (Lissner et al., 2000) and may not give a reliable representation.

Confounding Factors

The study outcomes may be affected by unconnected variables that can confound results and negatively affect internal validity. Including self-selecting patients being more motivated, the extent of social support, mobility levels and length of time being overweight or obese. The effects of these were not accounted for in this study. Comparison of results between this and other studies was difficult due to a wide variety of interventions.

4.8 Future Recommendations

This study has contributed to the evidence base in this area of research. Whilst the adult weight management programme was designed using the most up to date evidence and guidance, there is room for improvement. Recommendations are outlined below:

- More support should be provided to support pharmacy staff to recruit patients, a starting point would be sharing best practice from the pharmacies that were successful with recruitment in the current study
- A more in depth determination of 'readiness to change' should be carried out for patients being recruited onto the programme which should help to improve retention rates.
- A structured process should be put in place to contact patients who do not attend appointments and encourage them to re-arrange or attend the next appointment
- Patients who have lost weight during the programme should continue to be followed up regularly to support with weight maintenance.
- A standard computerised database should be developed and used locally to facilitate monitoring and audit within pharmacies.
- The GP computer systems should be developed so they are easier to use so the data required can easily be extracted.
- Other clinical outcomes and lifestyle factors could be measured to assess additional improvements as a result of the adult weight management programme.

4.9 Implications

The evaluation has provided evidence of an effective method of treating obesity within primary care. Following the completion of the adult weight management programme evaluation, information on the implementation, development and success of the programme will be disseminated within Birmingham and to other Primary Care Trusts and health care professionals. The evaluation will be used to inform future commissioning decisions within Birmingham with regards to obesity treatment programmes.

The Government is concerned about the levels of obesity in this country. The White Paper Healthy Lives, Healthy People: Our Strategy for Public Health in England (Department of Health, 2010), sets out how the Government plans to improve public health. The Department of Health will publish a follow-on document setting out how obesity will be tackled in the new public health and NHS systems. This study will be able to support and influence the decisions in Birmingham and other areas about the most effective services to commission to treat obesity in the new Public Health environment.

4.10 Conclusion

This study has highlighted that the adult weight management programme is effective, resulting in a significant decrease in weight, BMI and waist circumference and a significant increase in quality of life at 12 weeks and maintained 6 months post intervention. The pharmacy led programme appears more effective than the GP led programme demonstrating a significantly greater retention rate with a significant percentage of participants maintaining their weight loss 6 months post intervention. This study was carried out within the normal working environment of pharmacy and GP practice, therefore reflecting normal practice.

Offering a weight management programme delivered in a pharmacy setting opens up opportunities to support people in their local community to lose weight and maintain that weight loss, by being more accessible and approachable than a GP practice which has less flexible appointments and where it is harder to build a relationship with the client to maintain the support required.

Chapter 5 - References

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List of Appendices

Appendix 1.	Participant Information Sheet
Appendix 2.	Ethical approval from the Faculty of Applied and Health Sciences Research Ethics Committee at the University of Chester
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Appendix 4.	Topics addressed as part of the weight management programme
Appendix 5.	Measurement procedures
Appendix 6.	SF-12 health survey

Appendix 2.

Faculty of Applied and Health Sciences
Research Ethics Committee

10 February 2010

Dear Sarah

Study title: **Evaluation of an adult weight management service delivered by
pharmacies and GP practices**

FREC reference:376/09/SM/CENS

Version number: **2**

Thank you for sending the above-named application to the Faculty of Applied and Health Sciences Research Ethics Committee for review.

The application has been considered on behalf of the Committee by Steve Lewis as Lead Reviewer and reported to the Faculty Research Ethics Committee.

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form and supporting documentation.

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Application Form	1	November 2009
List of references	1	November 2009
CV of lead researcher	-	November 2009
Participant information sheet	2	January 2010
Consent form	2	January 2010
Notes on SF-12® questionnaire	1	November 2009
SF-12® questionnaire	-	2002
Measurement protocols	1	November 2009
Wording for promotional leaflet	1	November 2009
Correspondence regarding NHS ethical approval	-	October 2009
Response to FREC request for further clarifications	1	January 2010

With the Committee's best wishes for the success of this project.

Yours sincerely,

Prof. Cynthia Burek

Chair, Faculty Research Ethics Committee

Enclosures Standard conditions of approval.

c.c. Supervisor

FREC Representative